



1516 03 APR -2 A

April 1, 2003

Robert Lake  
Director, Office of Regulations and Policy  
Center for Food Safety and Applied Nutrition  
Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, Maryland 20852

Re: Docket No. 02N-0278 (Prior Notice of Imported Food)

Dear Mr. Lake:

The Corn Refiners Association, Inc. (CRA) appreciates the opportunity to provide comments on the U.S. Food and Drug Administration's (FDA) proposed rule regarding the prior notice of imported food under the Public Health Security and Bioterrorism Preparedness Act of 2002 (the Bioterrorism Act).

The Corn Refiners Association, Inc. is the national trade association representing the corn refining (wet milling) industry of the United States. Members of the Association produce food and industrial starches, sweeteners, ethanol, feed ingredients, vegetable oil, organic acids, amino acids and polyols using the corn wet milling process. The Association, and its predecessors, has served this important segment of American agribusiness since 1913. A list of our members is attached to these comments.

CRA strongly supports strengthening the safety and security of the U.S. food supply, and has worked diligently with its member companies to provide helpful and accurate food safety information to the public. We commend FDA for swiftly fulfilling its obligations under the Bioterrorism Act to avoid the undesirable statutory defaults included therein.

We would, however, like to express our concerns with the proposed prior notice of imported food rule. In the proposed rule, FDA lists among the information requirements for a prior notice "*the quantity described from smallest package size to largest container*". FDA has further stated that "*... in most circumstances information regarding imports is generated when the article to be imported is ordered or purchased, not when it is shipped to the United States.*" While this may be true in most cases, we do not think that FDA has sufficiently examined the veracity of this statement as it applies to bulk commodities, such as corn, wheat flour and vegetable oil. The quantity specified when a bulk commodity is ordered is an estimated weight. An actual amount is not known until the loading process is complete. For those facilities located less than 12 hours from a U.S. border, FDA's proposed requirement of notification by noon the prior day would result in an extremely high amendment rate. The difference in quantity in these circumstances is minimal. Amending a prior notice to reflect this change will result in

02N-0278

C 71

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
Docket Number 02N-0276  
April 1, 2003  
Page 2

Additionally, we believe the proposed rule requires clarification regarding the financial responsibility of all parties in the event of a shipment being held due to a foreign facility's failure to provide acceptable facility registration. 21 CFR 1.241(f) states: "... *the owner, purchaser, importer or consignee must arrange for storage of the article of food in an FDA-designated secure facility and must promptly notify FDA of this location. Any movement of the article to the facility must be accomplished under bond. Transportation and storage expenses shall be borne by the owner, purchaser, importer or consignee.*" The ambiguity of this statement suggests the importer may be held financially responsible for the lack of its vendor to register properly. The Bioterrorism Act does not provide adequate statutory language to suggest that an importer should be held responsible, either financially or through time investment, for a foreign facility's failure to register. We suggest that FDA hold the offending facility or its parent company solely responsible for any cost incurred by failure to register.

We thank you for the opportunity to provide FDA comments on the proposed rule to implement the food facility registration provision.

Sincerely,

A handwritten signature in black ink, appearing to read "Audra Erickson", written over the printed name.

Audra Erickson  
President

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
Docket Number 02N-0276  
April 1, 2003  
Page 3

**MEMBER COMPANIES**  
Corn Refiners Association, Inc.  
1701 Pennsylvania Avenue, N. W.  
Washington, D. C. 20006

Archer Daniels Midland Company  
P. O. Box 1470  
Decatur, IL 62525

Plants:

Cedar Rapids, Iowa  
Decatur, Illinois  
Clinton, Iowa  
Marshall, Minnesota  
Columbus, Nebraska

Cargill, Incorporated  
P. O. Box 9300  
Minneapolis, Minnesota 55440

Plants:

Blair, Nebraska  
Cedar Rapids, Iowa  
Eddyville, Iowa  
Dayton, Ohio  
Memphis, Tennessee  
Wahpeton, North Dakota  
Hammond, Indiana  
Decatur, Alabama  
Dimmitt, Texas

Corn Products International, Inc.  
5 Westbrook Corporate Center  
Westchester, Illinois 60154

Plants:

Argo, Illinois  
Stockton, California  
Winston-Salem, North Carolina

National Starch and Chemical Company  
P. O. Box 6500  
Bridgewater, New Jersey 08807

Plants:

Indianapolis, Indiana  
North Kansas City, Missouri

Penford Products Co.  
(A company of Penford Corporation)  
P. O. Box 428  
Cedar Rapids, Iowa 52406

Plant:

Cedar Rapids, Iowa

Roquette America, Inc.  
1417 Exchange Street  
Keokuk, Iowa 52632

Plant:

Keokuk, Iowa

A. E. Staley Manufacturing Company  
(A subsidiary of Tate & Lyle, PLC)  
P. O. Box 151  
Decatur, Illinois 62525

Plants:

Decatur, Illinois  
Lafayette, Indiana (2)  
Loudon, Tennessee